MAY 3 0 2003

K031266

TERUMO MEDICAL PRODUCTS – HANGZHOU CHINA
SURSHIELD™ SAFETY WINGED INFUSION SET
Section II – Summary and Certification

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION PERTAINING TO SUBSTANTIAL EQUIVALENCE

DEVICE NAME

Proprietary Name

SURSHIELD™ Safety Winged Infusion Set

Classification Name

Intravascular Administration Set (80FPA)
21CFR, Section 880.5440
Classification: Class II

Common Name

Intravascular Administration Set

INTENDED USE

The Surshield Safety Winged Infusion Set is intended for intravenous administration of fluids and/or withdrawal of blood specimens using a syringe, luer adapter, or other compatible/appropriate devices. The winged infusion set may be used for any patient population with consideration given to patient size. Additionally, after withdrawal of the needle from the patient's vein, the shield cover can be manually activated to cover the needle to minimize risk of accidental needlestick.

DESCRIPTION

The Surshield Safety Winged Infusion Set is a sterile, single-use device consisting of a needle attached to a winged type hub, tubing, connector and connector cap, and a hinged shield cover that attaches to the wing just below the needle-to-wing junction. The Surshield Safety Winged Infusion Set manufactured by Terumo Medical Products in Hangzhou, China is the same as the Surshield Winged Infusion Set manufactured by Terumo Corporation in Kofu, Japan and cleared under K010103.

The shield cover can be turned 180 degrees on the hinge. As the needle is removed from the patient's vessel, the user's finger actively pushes the shield cover until it latches onto needle using a one- or two- handed technique. An audible click is noted upon activation. The shield cover is designed to allow the user's finger to remain behind the needle point so that the risk of needle stick injury is minimized. The shield cover is transparent for easy confirmation of the needle held in it.

The device possesses both 90 and 300mm length tubing.

SUBSTANTIAL EQUIVALENCE

The Surshield Safety Winged Infusion Set manufactured by Terumo Medical Products in Hangzhou, China is substantially equivalent to the Surshield Winged Infusion set manufactured by Terumo Corporation in Kofu, Japan and cleared under K010103.

PRINCIPLE OF OPERATION/TECHNOLOGY

Both devices are operated manually.

MATERIALS

The materials used in the Surshield Safety Winged Infusion Set manufactured by Terumo Medical Products in Hangzhou, China are the same as the predicate devices, which do not raise any new issues of safety or effectiveness.

SPECIFICATIONS

Cannula gauge	Color code	Product code	Winged type hub	Cannula length	Tube length
19G	Cream	SV*S19BL	C type	3/4"(19mm)	300mm
		SV*S19DL	D type	5/8"(16mm)	
		SV*S19BLS	C type	3/4"(19mm)	90mm
21G	Green	SV*S21BL	C type	3/4"(19mm)	300mm
		SV*S21DL	D type	5/8"(16mm)	
		SV*S21BLS	C type	3/4"(19mm)	90mm
23G	Light blue	SV*S23BL	C type	3/4"(19mm)	300mm
		SV*S23DL	D type	5/8"(16mm)	
		SV*S23BLS	C type	3/4"(19mm)	90mm
25G	Orange	SV*S25BL	C type	3/4"(19mm)	300mm
		SV*S25DL	D type	5/8"(16mm)	
		SV*S25BLS	C type	3/4"(19mm)	90mm

PERFORMANCE

The following tests were performed on the Surshield Safety Winged Infusion Set manufactured by Terumo Medical Products in Hangzhou, China:

- Shield cover/Needle Locking Strength
- Break strength of the shield cover joint
- Force to lock the needle in the shield cover (Force to activate safety feature)
- Puncture Resistance of Shield Cover
- Flow Rate
- Priming Volume
- Wing to Tubing Connection Strength
- Tubing to Connector Connection Strength
- Needle to Wing Connection Strength
- Needle Penetration Resistance
- Wing Needle Protector Fit
- Leak Test
- Blockage Test

Additionally, a risk analysis was conducted and no new issues were identified since the Surshield China device is identical to the cleared Surshield Kofu. None of the data raises any new issues of safety and effectiveness.

The Surshield Safety Winged Infusion Set manufactured by Terumo Medical Products in Hangzhou, China is substantially equivalent to the Surshield Winged Infusion set manufactured by Terumo Corporation in Kofu, Japan and cleared under K010103.

ADDITIONAL SAFETY INFORMATION

The sterilization conditions are validated according to EN550 to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Ethylene Oxide residual levels resulting from EtO sterilization will not exceed the maximum residue levels proposed for Part 821 of Title 21 in the Federal Register Notice issued June 23, 1978, and indicated as follows:

Ethylene Oxide	25 ppm
Ethylene Chlorohydrin	25 ppm

The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing. Results of the testing demonstrate that the blood contacting materials are biocompatible.

CONCLUSION

The Surshield Safety Winged Infusion Set manufactured by Terumo Medical Products in Hangzhou, China is substantially equivalent to the Surshield Winged Infusion set manufactured by Terumo Corporation in Kofu, Japan and cleared under K010103 with respect to intended use, design, technology/principles of operation, materials and performance. Differences between the devices do not raise any new issues of safety or effectiveness.

Date Prepared: 04/17/03

Prepared by: Barbara Smith
Sr. Regulatory Affairs Specialist
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Elkton, MD 21921
Phone: 410-392-7241

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2003

Ms. Barbara Smith
Senior Regulatory Affairs Specialist
Terumo Medical Corporation
125 Blue Ball Road
Elkton, Maryland 21921

Re: K031266
Trade/Device Name: SURSHIELD™ Safety Winged Infusion Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: April 18, 2003
Received: April 22, 2003

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031266

510(k) Number (if known):

Device Name: SURSHIELD™ SAFETY WINGED INFUSION SET

Indications For Use:

The Surshield Safety Winged Infusion Set is intended for intravenous administration of fluids and/or withdrawal of blood specimens using a syringe, luer adapter, or other compatible/appropriate devices. The winged infusion set may be used for any patient population with consideration given to patient size. Additionally, after withdrawal of the needle from the patient's vein, the shield cover can be manually activated to cover the needle to minimize risk of accidental needlestick.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031266